(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38818, July 25, 2001]

§ 890.5700 Cold pack.

(a) *Identification.* A cold pack is a device intended for medical purposes that consists of a compact fabric envelope containing a specially hydrated pliable silicate gel capable of forming to the contour of the body and that provides cold therapy for body surfaces.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.5710 Hot or cold disposable pack.

(a) *Identification.* A hot or cold disposable pack is a device intended for medical purposes that consists of a sealed plastic bag incorporating chemicals that, upon activation, provides hot or cold therapy for body surfaces.

(b) *Classification.* Class I (general controls). Except when intended for use on infants, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 890.9.

[48 FR 53047, Nov. 23, 1963, as amended at 65 FR 2322, Jan. 14, 2000]

§ 890.5720 Water circulating hot or cold pack.

(a) *Identification.* A water circulating hot or cold pack is a device intended for medical purposes that operates by pumping heated or chilled water through a plastic bag and that provides hot or cold therapy for body surfaces.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59231, Nov. 3, 1998]

§ 890.5730 Moist heat pack.

(a) *Identification.* A moist heat pack is a device intended for medical purposes that consists of silica gel in a fabric container used to retain an elevated temperature and that provides moist heat therapy for body surfaces.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38818, July 25, 2001]

§ 890.5740 Powered heating pad.

(a) *Identification.* A powered heating pad is an electrical device intended for medical purposes that provides dry heat therapy for body surfaces. It is capable of maintaining an elevated temperature during use.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E part 807 of this chapter subject to § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59231, Nov. 3, 1998]

§ 890.5765 Presssure-applying device.

(a) *Identification.* A presssure-applying device is a device intended for medical purposes to apply continuous pressure to the paravertebral tissues for muscular relaxation and neuro-inhibition. It consists of a table with an adjustable overhead weight that, in place of the therapist's hands, presses on the back of a prone patient.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in

subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 59 FR 63015, Dec. 7, 1994; 66 FR 38818, July 25, 2001]

§ 890.5850 Powered muscle stimulator.

(a) *Identification.* A powered muscle stimulator is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area.

(b) *Classification.* Class II (performance standards).

§ 890.5860 Ultrasound and muscle stimulator.

(a) *Ultrasound and muscle stimulator for use in applying therapeutic deep heat for selected medical conditions*—(1) *Identification.* An ultrasound and muscle stimulator for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies. The device also passes electrical currents through the body area to stimulate or relax muscles.

(2) *Classification.* Class II (performance standards).

(b) *Ultrasound and muscle stimulator for all other uses*—(1) *Identification.* An ultrasound and muscle stimulator for all other uses except for the treatment of malignancies is a device that applies to the body ultrasonic energy at a frequency beyond 20 kilohertz and applies to the body electrical currents and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues and the stimulation or relaxation of muscles as described in paragraph (a) of this section.

(2) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP for a device described in paragraph (b) of this section is required to be filed with the Food and Drug Administration on or before July 13, 1999 for any ultrasound and muscle stimulator described in paragraph (b) of this section that was in commercial distribution before May 28, 1976, or that has, on or before July 13, 1999, been found to be substantially equivalent to an ultrasound and muscle stimulator described in paragraph (b) of this section that was in commercial distribution before May 28, 1976. Any other ultrasound and muscle stimulator described in paragraph (b) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53047, Nov. 23, 1983, as amended at 52 FR 17742, May 11, 1987; 64 FR 18331, Apr. 14, 1999]

§ 890.5880 Multi-function physical therapy table.

(a) *Identification.* A multi-function physical therapy table is a device intended for medical purposes that consists of a motorized table equipped to provide patients with heat, traction, and muscle relaxation therapy.

(b) *Classification.* Class II (performance standards).

§ 890.5900 Power traction equipment.

(a) *Identification.* Powered traction equipment consists of powered devices intended for medical purposes for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the patient's body.

(b) *Classification.* Class II (performance standards).

§ 890.5925 Traction accessory.

(a) *Identification.* A traction accessory is a nonpowered accessory device intended for medical purposes to be used with powered traction equipment to aid in exerting therapeutic pulling forces on the patient's body. This generic type of device includes the pulley, strap, head halter, and pelvic belt.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current